

## **REMARKS**

### **Claim Objections**

Claim 20 is cancelled without prejudice or disclaimer.

### **Rejections under 35 USC § 102**

Claims 1, 5-6, 14-16, 20 and 22 were rejected as allegedly anticipated by McGee, US 5,198,216, and claims 1, 2, 5-6 14, 16, 20 and 22 were rejected as allegedly anticipated by Lockett, US 5,626,884.

Claim 1 was amended to recite features of claims 2, 3, and 5. No section 102 rejection was made with respect to claim 3 by either reference. For at least this reason, the anticipation rejections are overcome.

### **Rejections under 35 USC § 103**

Claims 3-4, 17-19, 21 and 23 were rejected as allegedly unpatentable over Lockett, US 5,626,884, in view of Bailey, US 5,997,915.

The Office Action alleges that Bailey provides motivation for the replacement of folic acid in the composition of Lockett with folic acid derivatives. Applicants respectfully disagree. No teaching or suggestion is made in Lockett for the replacement of folic acid in his compositions aimed at treating sickle cell crisis. Lockett teaches the use of a very specific composition requiring a large group of ingredients, i.e., "vitamin A, vitamin B-1, vitamin B-2, vitamin B-6, vitamin B-12, vitamin C, vitamin D, vitamin E, niacinamide, para-aminobenzoic acid (PABA), pantothenic acid, choline bitartrate, inositol, rutin, citrus bioflavonoid complex, betaine hydrochloride, hesperidin complex, folic acid, biotin, calcium, iron, magnesium, zinc, potassium, manganese, iodine, chromium, selenium, and a pharmaceutically acceptable carrier" (emphasis added) (see column 2, lines 44-52), for a highly specific use, i.e., to reduce the incidence and severity of sickle cell disease crisis (see column 2, lines 40-44) at very specific dosage regimens, i.e., "at or just below critical

saturation levels” (see column 2, lines 53-59), which may exceed those conventionally used as dietary and nutritional supplements (see column 2, lines 60-63). One of ordinary skill in the art would have lacked the motivation to combine the teachings of such a highly specific invention, that specifically states that the levels provided may exceed dietary and nutritional needs, with the broad teachings of Bailey which recites “breakfast foods such as prepared cereals, toaster pastries and breakfast bars; infant formulas; dietary supplements and complete diet and weight-loss formulas and bars; animal feed (for example pet foods) and animal feed supplements (such as for poultry feed),” as well as multivitamin preparations. See abstract.

It would not be reasonable for one interested in treating the serious disease, sickle cell crises, using the detailed and specific formulation of Lockett to modify the latter based on the general Bailey disclosure which deals with folate nutrition and not sickle cell treatment at all. One dealing with sickle cell disease would find Bailey totally irrelevant. Similarly, one interested in folate nutrition would not look to sickle cell treatments for relevant information. There simply is no motivation to combine these references.

Moreover, there is no apparent reason why one of ordinary skill in the art would have considered Lockett as relevant, i.e., analogous prior art, to the present invention, especially to independent claim 15, which is directed to a food or food supplement. One of ordinary skill in the art of foods or food supplements would have lacked the motivation to consider a reference that deals with a highly specific and serious disease such as sickle cell disease crises for guidance on how to formulate general compositions containing certain methyl transporters as listed in the claims.

In *In re Clay*, 966 F.2d 656, 23 USPQ.2d 1058 (CAFC 1992) the Federal Circuit held that a prerequisite to an obviousness determination is to define the art which the subject matter sought to be patented pertains, i.e., whether it is analogous art, i.e., whether the art is too remote to be treated as prior art. The two criteria identified were whether the art is from the same field of endeavor, or whether the reference, if not in the same field of endeavor, still is reasonably pertinent to the particular problem with which the inventor is involved.

The court held that the two prior art references could not be considered to be in the same field of endeavor merely because they relate to the petroleum industry. In the present

case, the relationship between the two inventions may be even more remote than in *Clay*. Locket and the present invention cannot be said to belong to the same field of endeavor merely because both compositions can be administered to a human, for example. Lockett relates to a highly specific disease involving patients while the present invention is directed to broad uses (see claim 1) and to a food or food supplement (see claim 15) for use by anyone.

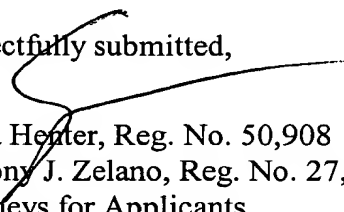
In *Clay*, the court specifically looked at the differing environments the two inventions were to operate in, i.e., temperature and pressure. Here too, the two inventions are intended to operate under very different conditions. Locket is directed to a use that is a serious disease which requires that a composition of many ingredients be administered at a very high dose (see discussion above). Locket specifically points out that such doses may exceed dietary or nutritional needs. On the other hand, the present invention is provided for more general uses and is administrable under a large variety of conditions at a variety of doses. With respect to claim 15, directed specifically to a food or food supplement, in which use one of ordinary skill in the art would not be motivated to administer the composition at or just below critical saturation levels.

Whether the references are reasonably pertinent to the particular problem with which the inventor is involved also requires a look at the purpose of the prior art inventions. If the references are directed to a different purpose than the current invention, the inventor would accordingly have had less motivation or occasion to consider them. Lockett clearly addresses a problem far and remote from the problems of the present invention, thereby not providing the motivation or occasion for one of skill in the art to consider it. A person of ordinary skill in the art would not reasonably have expected to solve a problem relating to compositions, such as food or food supplement compositions, by considering a reference dealing with the highly serious disease of sickle cell crisis.

Accordingly, one of ordinary skill in the art would have lacked both the motivation to combine the teachings of Locket with Bailey and also to consider the Locket reference as relevant art to the present invention. Without such motivation to combine the references and/or to consider them as relevant prior art, the obviousness rejection is improper. Reconsideration is respectfully requested.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

  
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